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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; and THE DISTRICT OF COLUMBIA,

ex rel. ZACHARY SILBERSHER,

Plaintiffs,

vs.

JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, JOHNSON & JOHNSON, and BTG INTERNATIONAL LTD.

Defendants.

Civil Action No. 19-12107 (KM) (JBC)

REPLY IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS SECOND AMENDED COMPLAINT

Motion Date: Nov. 4, 2019

(Oral Argument Requested)

Document electronically filed

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes and Regulation

Legislative History

Other Authorities

PRELIMINARY STATEMENT

In our Motion to Dismiss ("Motion"), we presented two principal grounds for dismissal: (1) the prior public disclosure of Relator's claims; and (2) the insufficiency of Relator's pleadings under the FCA's well-established legal boundaries. Relator's Opposition to Defendants' Motion to Dismiss ("Opposition") does not cure either.

As to the first, Relator fails to identify a single fact pled in the Second Amended Complaint ("SAC") discovered from non-public sources. The public disclosure bar is "wide-reaching" with a "generally broad scope," *Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 563 U.S. 401, 408 (2011); *accord U.S. ex rel. Advocates for Basic Legal Equal., Inc. v. U.S. Bank, N.A.*, 816 F.3d 428, 430, 432 (6th Cir. 2016), as its very point is to reserve the FCA's generous award-sharing provisions for relators with genuine "insider" or otherwise undisclosed knowledge, while excluding parasitic claims and free-riders. *E.g.*, *Ebeid ex rel. U.S. v. Lungwitz*, 616 F.3d 993, 999 (9th Cir. 2010). The public disclosure bar readily filters out Relator's claims.

As to the second, Relator urges an extremely broad ("capacious," as he puts it) construction of the FCA that advances theories never before recognized, abandons core pleading requirements, and is irreconcilable with the Supreme Court's decision in *Universal Health Services, Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989 (2016). Relator's construction would reach any allegation of "fraud" touching the federal government, no matter how attenuated its connection to any actual claim for payment. The FCA emphatically is *not* the "all-purpose anti-fraud" statute that Relator needs it to be. *Id.* at 2003. The statute is strong medicine, imposing "essentially punitive" penalties, *id.* at 1996, but only where Congress targeted it.

Because Relator's *third attempt* to plead his claims still fails to substantiate either his ability to bring these claims, or their legal sufficiency, the SAC should be dismissed with prejudice.

ARGUMENT

I. RELATOR'S CLAIMS ARE PRECLUDED BY THE PUBLIC DISCLOSURE BAR

The FCA's public disclosure bar discourages "opportunistic litigation" by relators cribbing publicly available information. *Schindler Elevator*, 563 U.S. at 413. That is all Relator has done,

and the FCA does not reward such opportunism.

A. Relator's Allegations Were Publicly Disclosed Through Enumerated Channels.

Relator stripped his factual allegations from three principal public sources—*inter partes* review ("IPR") petitions filed with the Patent Trial and Appeal Board ("PTAB"), patent prosecution submissions filed with the U.S. Patent and Trademark Office ("USPTO"), and various publicly available articles—each of which comes within one or more of the FCA's enumerated public disclosure channels. Mot. 10-13. Relator does not dispute the sources of his "facts," but rather advances an erroneously cramped view of each statutory public disclosure channel.

Starting with the IPR proceedings, as explained in our Motion, IPRs fit comfortably within *both* 31 U.S.C. § 3730(e)(4)(A)(i), which captures disclosures "in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party," *and* § 3730(e)(4)(A)(ii), which captures disclosures made "in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation."

Relator contends that IPRs are not qualifying disclosures because in an IPR the Government acts only in an adjudicatory capacity and is therefore not "a party." Opp. 35-37. Not so. As the Federal Circuit—which reviews IPRs—has recognized, the Government plays a "central role" in IPRs "as a superior sovereign to reconsider a prior administrative grant." *Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322, 1327-29 (Fed. Cir. 2018). Relator's attempt to dismiss *Saint Regis* as merely a sovereign immunity case, Opp. 36-37, ignores the Federal Circuit's reasoning and analysis. *Saint Regis* contrasted private suits brought in an Article III or agency forum, where sovereign immunity does apply, with enforcement actions and similar proceedings, such as IPRs, where sovereign immunity does not apply. 896 F.3d at 1327-28. As the Federal Circuit explained, IPRs thus share critical attributes with both a hearing in which the Government is a party under § 3730(e)(4)(A)(i) and a federal hearing under § 3730(e)(4)(A)(ii).

Relator's reliance on *Return Mail, Inc. v. USPS*, 139 S. Ct. 1853 (2019)—in which the Supreme Court held the Government itself could not initiate an IPR—is misplaced. Opp. 35-36. As the Federal Circuit ruled ***after*** *Return Mail*, while the USPTO's:

> enlistment of third parties in IPR has made the process less of an agency-led, inquisitorial process for reconsidering patents and more of a party-directed, adversarial process … that does not disturb the basic purpose of the proceeding, namely, to reexamine an earlier agency decision[,] convinc[ing] us that IPR is *more like an agency enforcement action than a civil suit brought by a private party*.

Regents of the Univ. of Minn. v. LSI Corp., 926 F.3d 1327, 1338-39 (Fed. Cir. 2019) (emphasis added). Thus, *Return Mail* did not change the Federal Circuit's controlling view.

Relator's concern that this understanding will sweep in every agency action, Opp. 35-37, is unfounded. Relator focuses exclusively on § 3730(e)(4)(A)(i), which requires the United States to be a party, but ignores § 3730(e)(4)(A)(ii), which includes federal hearings regardless of whether the United States is a party. Opp. 38. Between them, these provisions capture proceedings through which the Government would likely receive notice of relevant disclosures and carve out those where it would not. The former, (A)(i), concerns judicial-type hearings where the Government provides a neutral adjudicator and, where, unless also a party-in-interest, the Government may lack notice. The latter, (A)(ii), captures federal administrative proceedings in which the Government has a more inquisitorial role, where it is much more likely to note facts disclosed. As described in *Saint Regis* and *LSI Corporation*, *supra*, the Government in an IPR is not adjudicating the disposition of property as between private parties, but rather is entertaining the moving party's contention that the Government should reconsider and rescind its grant of a patent to another.

Relator resists the fact that documents filed in conjunction with IPR proceedings and patent prosecutions, when made publicly available through databases maintained by the USPTO (Public PAIR) and the PTAB, are federal "reports" under § 3730(e)(4)(A)(ii). Mot. 12-13. Relator's own authority, *Schindler Elevator*, recognizes that a "report" includes "something that gives information" or "a 'notification'" or "[a]n official or formal statement of facts or proceedings," 563 U.S. at 407-08, which is precisely what PAIR and the PTAB docket do. PAIR compiles and synthesizes information about patent histories for the public, and the PTAB maintains an official report of all proceedings under the America Invents Act, including documents submitted pursuant to those proceedings, on its website.

Contrary to Relator's concern, Defendants' position does not implicate "all private federal

litigation (available on PACER)." Opp. 38. PACER is maintained by the federal judiciary, the branch of government concerned with affording all parties (private and Government) an independent and neutral forum to adjudicate disputes, and there is no reason to think that "Federal report" captures judicial information generally. Public PAIR and the PTAB docket conversely are made available to the public, free of charge, by the USPTO. As an executive agency, the USPTO is expected to gather and disseminate facts, form views, and help shape executive policy in part through "Federal reports."[1] Recognizing federally maintained databases for what they are would not "nullify" any amendments to the FCA. *Contra* Opp. 38.

Our Motion separately demonstrated that Relator's essential factual allegations were also reported in "news media," another source of qualifying public disclosures. 31 U.S.C. § 3730(e)(4)(iii). Here again, Relator advances an unduly cramped construction. Numerous courts have ruled that "information contained on publicly available websites can be public disclosures within the meaning of the FCA." *U.S. ex rel. Repko v. Guthrie Clinic, P.C.*, No. 3:04-CV-1556, 2011 WL 3875987, at *7 (M.D. Pa. Sept. 1, 2011) (collecting cases). As another court in this District has explained, while "not all information in the public domain" falls within the bar, "news media" "at minimum" includes publicly available websites

> where the information provided is to some extent curated—that is, where the authors or editors of the website actively gather and disseminate information, provide search tools for the public to analyze data, provide some editorial content, or exercise some control over the information provided—and where the information bears at least some of the 'indicia of reliability or substantiation' common to more traditional news media sources.

U.S. ex rel. Customs Fraud Investigations, LLC v. Victaulic Co., No. 13-2983, 2014 WL 4375638, at *10 (E.D. Pa. Sept. 4, 2014).

Relator relies on a single, non-binding case for the proposition that "news media" should not include "broad swaths of the Internet." Opp. 38 (citing *U.S. ex rel. Integra Med Analytics LLC*

[1] *See* https://www.uspto.gov/about-us (agency tasked with "advis[ing] the president of the United States, the secretary of commerce, and U.S. government agencies on intellectual property (IP) policy, protection, and enforcement").

v. Providence Health & Servs., CV 17-1694 PSG, 2019 WL 3282619 (C.D. Cal. July 16, 2019)). Of course, no one claims that the public disclosure bar applies based on disclosures made in the darkest reaches of the internet. And Relator ignores the "general consensus in the federal courts" that "news media" goes beyond "traditional[]" news sources. 2019 WL 3282619, at *13. As those courts recognize, "news media" readily captures targeted or curated sources of information including scholarly journals, scientific studies, business articles, competitor websites, and data collected and disseminated by the government through websites and databases. *See, e.g.*, *Victaulic*, 2014 WL 4375638, at *10 ("news media" includes data collected and disseminated to the public by the government); *see also U.S. ex rel. Moore & Co. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 302-03 (3d Cir. 2016) ("news media" "describes a multitude of sources that would seldom come to the attention of the Attorney General"); *In re Plavix Mktg., Sales Practices & Prods. Liab. Litig.*, 123 F. Supp. 3d 584, 596 (D.N.J. 2015) (online publications are "news media"); *Repko*, 2011 WL 3875987, at *7 ("news media" includes scholarly or scientific periodicals). Relator has provided no basis to reject any of the readily available public sources cited in the Motion.[2]

Similarly, Relator provides no basis to reject authorities holding that articles identifying the existence of an IPR effect a public disclosure. Opp. 39. When the news media discloses the existence of a lawsuit and provides the reader with sufficient information to access the underlying material, the underlying allegations are disclosed. Mot. 14; *see also U.S. v. Kimberly-Clark Corp.*, No. LA CV 14-08313 JAK, 2017 WL 10439028, at *6 (C.D. Cal. July 14, 2017).[3] Here, news

[2] Relator faults Defendants for citing "literally no case holding that IPR filings or patent prosecution submissions" fall within the public disclosure bar. Opp. 38-39. But this further exposes the bankrupt nature of Relator's Complaint; few relators have so plainly flouted the public disclosure bar by trolling through public USPTO databases to stitch together FCA complaints. Relator's public sources fit comfortably within the FCA's public disclosure bar.

[3] *Proctor* makes clear it concerned a complaint disclosed through a *Law360* article that contained allegations of fraud at issue in that case—not the *Law360* article. *U.S. ex rel. Proctor v. Safeway, Inc.*, No. 11-cv-3406, 2016 WL 7017231, at *13-14 (C.D. Ill. Dec. 1, 2016). Moreover, the *Proctor* court did not find that there was not a public disclosure—rather, it concluded that there was not a "*prior* public disclosure," because the *Proctor*-relator's first complaint pre-dated the disclosure of the separate relator's complaint. *Id.* at 14 (emphasis added).

articles and SEC filings did precisely that by reporting the IPR proceedings, parties, filing dates, and sometimes even docket information.[4] Mot. 14.

B. Relator Ignores The Controlling Legal Framework For Determining Whether There Was A Public Disclosure.

Relator disputes neither the public nature of his sources, nor that the vast majority of his allegations were publicly reported. Rather, he nitpicks at the framing of a handful of these disclosures, amounting at best to an argument over the inferences they fairly support. However, as shown in our Motion, Relator's "allegations" of wrongdoing and the underlying "transactions" that would "raise[] an inference of fraud consist[ing] of both the allegedly misrepresented facts and the allegedly true state of affairs" were clearly and previously publicly disclosed. *U.S. v. Omnicare, Inc.*, 903 F.3d 78, 83 (3d Cir. 2018). Relator's Opposition advances irrelevant and inaccurate distinctions between the public record and the SAC, and demands a degree of precise parallelism between the two that is contrary to controlling FCA precedent.

Relator argues first that there could not have been any public disclosure because "IPRs do not allege fraud." Opp. 32. But regardless of whether a party in an IPR may plead a fraud claim, Relator cites no authority, nor is there any, hinging public disclosure on use of the term "fraud" or the pleading of a fraud claim. There is not even any requirement that the alleged fraud itself be disclosed. Rather, under the "X+Y=Z" approach, it is sufficient that the "X" (the misrepresented facts) and the "Y" (the true state of affairs) are disclosed—the "Z" (the alleged fraud) is not required. *Omnicare*, 903 F.3d at 83-84. Relator's argument that Defendants fail to identify any document publicly disclosing Defendants' purported failure to tell the USPTO the real (in Relator's view) reasons for Zytiga's commercial success, Opp. 34, misunderstands the governing legal framework. What Relator complains is lacking is the "Z." But, the public disclosure bar requires only the public disclosure of the "X" and "Y"—information sufficient to "put the government on the trail" of an alleged fraud. *U.S. ex rel. Schumann v. AstraZeneca Pharm. LP*,

[4] The disclosure of a lawsuit or IPR in a report prepared for the federal government pursuant to federal regulations, such as SEC filings, *see U.S. ex rel. Calilung v. Ormat Indus., Ltd.*, No. 3:14-CV-00325-RCJ-VPC, 2015 WL 1321029, at *16 (D. Nev. Mar. 24, 2015), is no different.

No. 03-CV-5423, 2013 WL 300745, at *7 (E.D. Pa. Jan. 25, 2013).

Relator attempts to distinguish the SAC from the public sources used to compile it, arguing that no qualifying source reported that Defendants had failed to disclose to the USPTO: (1) that Xtandi had not received FDA approval for the chemo-naïve market; (2) that the '213 Patent was responsible for Zytiga's commercial success; or (3) that other facts contributed to Zytiga's commercial success. Opp. 33-34. But as to each of these, our Motion detailed how the "false" state of facts and their "true" counterparts were publicly disclosed. *See* Mot. 13-20.

Relator criticizes Defendants for not stating affirmatively that Xtandi had not been approved for chemo-naïve patients. Opp. 33-34. But this allegedly material and omitted fact was widely known and published by the FDA in its "Drugs@FDA" database, which provides "patient information, labels, approval letters, reviews, and other information" on approved drug products. *See* https://www.fda.gov/drugs/drug-approvals-and-databases/about-drugsfda. Indeed, federal law requires the Government to publish this information, *see* 21 U.S.C. § 355(l)(2), and both the database and the Government's postings constitute "Federal reports" under § 3730(e)(4)(A)(ii). *Cf. U.S. ex rel. Conrad v. Abbot Labs., Inc.*, No. 02-11738-RWZ, 2013 WL 682740 (D. Mass. Feb. 25, 2013). Fatal to Relator's argument, contemporaneous published material for Xtandi uniformly specifies the indication for chemo-refractory patients.[5] *See* Request for Judicial Notice ("RJN"), Exs. PP (Drugs@FDA page for Xtandi), QQ (Approval Letter), RR (Summary Review).

Relator similarly asserts Defendants failed to flag "the '213 blocking patent" and other "facts relating to Zytiga's commercial success" for the USPTO in connection with any commercial success presentation. Opp. 34. Again, Relator does not dispute that these were, in fact, disclosed. Rather, he argues that they were not disclosed at the right time or in the right location. *Id.* Relator confuses whether the information was disclosed to the USPTO in an appropriate way with whether the information was publicly disclosed at all for purposes of the FCA public disclosure bar. As to the latter, it is irrelevant how the information was disclosed to the USPTO so long as it was made

[5] And, with respect to the public disclosure bar, Relator ignores documents reporting that Xtandi was approved for the chemo-naïve market *after* the June 4 submission. Mot. 18; Opp. 33.

publicly available through an FCA approved channel. Because Relator's allegations and transactions were all publicly disclosed through proper sources, the public disclosure bar applies.

C. Relator Is Not An Original Source.

Lastly, Relator may survive the bar only if he credibly pleads that he is an "original source" contributing "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions." 31 U.S.C. § 3730(e)(4)(B). Relator, however, offers only the conclusory assertion that he is an "original source" who possesses "particular knowledge and expertise," and fails to cite to *anything* in the SAC to substantiate this claim. Opp. 39-40. The only support Relator offers is his claim to have somehow "uncovered" the FDA approval dates for Xtandi. *Id.* This, however, required only consulting the Drugs@FDA database.

Relator's former counsel disclosed the genesis of Relator's complaint in a filing in a related antitrust case also pending before the Court, where he described how Relator and his counsel "spent months combing through the file wrapper for the '438 Patent and uncovering the misrepresentations to the Patent Office that resulted in the first filing in this matter in *Silbersher*." *See* Mot. 5-6, *La. Health Servs. v. Janssen Biotech.*, No. 2:19-cv-14146-KM-KBC (D.N.J. Aug. 20, 2019), ECF No. 92-2. As Judge Donato (N.D. Cal.) observed about Relator's identical complaint involving a different drug, which suit Relator similarly culled from patent records, "Anyone in the world could have filed this case … My grandmother could have filed this case." *See* Hannah Albarazi, *'My Grandmother Could Have Filed This,' Valeant Judge Says*, LAW360 (Aug. 8, 2019), https://www.law360.com/articles/1186843/-my-grandmother-could-have-filed-this-valeant-judge-says; *see also U.S. ex rel. Silbersher v. Valeant Pharm. Int'l, Inc.*, No. C 18-1496(JD) (N.D. Cal. filed Mar. 8, 2018). Here too, Relator adds nothing material to the public documents that he and his lawyers read and then turned into an FCA complaint.

II. RELATOR FAILS TO PLEAD ESSENTIAL ELEMENTS OF HIS CLAIMS

A. Relator Fails To Plead A False Claim For Payment.

A false claim for payment is "the *sine qua non* of [an FCA] violation." *U.S. ex rel. Bartlett v. Tyrone Hosp., Inc.*, 234 F.R.D. 113, 124 (W.D. Pa. 2006). Our Motion demonstrated Relator's

failure to plead any recognized FCA theory of falsity. *See* Mot. 23-30. Relator now asserts three: (1) that Defendants "implicitly certified the prices they were charging were not tainted by fraud"; (2) that "upstream fraud" on the USPTO "tainted downstream claims for payment"; and (3) that the patent application was itself a false claim. Opp. 8-9. Each theory fails as a matter of law.

1. Relator Fails To Plead An Implied False Certification.

Relator abandons any claim that Defendants made an *express* false certification, Opp. 8-9, leaving only an *implied* false certification. As to that, Relator claims "Defendants implicitly certified the prices they were charging were not tainted by fraud." Opp. 8. Specifically, he argues, drug prices must be "fair and reasonable," which they cannot be if inflated by patent fraud. Thus, Relator contends, in allegedly submitting claims for reimbursement, Defendants necessarily implied that their prices were "fair and reasonable," further implying that their underlying patent has been properly issued. Opp. 15-18. This theory fails for two independent reasons.

First, to sustain a claim of *implied* false certification, a relator should identify "specific representations" made in connection with a claim for payment on which to hang the implication. Mot. 24-26. Relator, however, identifies no such representation. Relator attempts to square his claims with *Escobar*, Opp. 15-17, where the defendant had submitted claims using billing codes and identification numbers that corresponded to particular services and service providers. The express use of these codes and identification numbers implied the provision of these services by certain providers that had not, in fact, been provided, thereby making the claims misleading and false. 136 S. Ct. at 2000-01. Relator here identifies nothing analogous.

Instead, relying on *U.S. ex rel. Simpson v. Bayer Corp.*, 376 F. Supp. 3d 392 (D.N.J. 2019), Relator argues that "specific representations" are not required and the mere submission of a claim is all that is necessary. Opp. 17-18. As explained in our opening brief, however, *Simpson* is inconsistent with *Escobar*, relevant circuit authority, and the weight of post-*Escobar* jurisprudence. Mot. 25-26 & n.33. The relator in *Simpson* contended that by submitting a claim for payment, the claimant was certifying it was entitled to payment, an obviously material requirement. 376 F. Supp. 3d at 406. Even in that case, then-Chief Judge Linares allowed the

claim to proceed only given the additional weight of the Anti-Kickback Statute. *Id.* at 408 (discussing 42 U.S.C. § 1320a-7b(g)). Here, Relator proposes a very different implication; that in seeking reimbursement, Defendants impliedly certified that their products were based on a properly issued patent. Opp. 16-18. That is a far greater leap, yet Relator pleads no "specific representations" made by Defendants in submitting claims for payment giving rise to a "half-truth" or otherwise supporting a false implication as discussed in *Escobar*, 136 S. Ct. at 1995, 2001.

Second, as discussed in our Motion, the requirement that federal drug prices be "fair and reasonable" simply cannot bear the weight Relator puts on it. That phrase refers not to any subjective notion of "fairness" or "reasonableness," but rather to the result of applying a specific formula to specific inputs. Mot. 26-30. Relator has not pled that Defendants erred in any way in supplying the required market data, and admits as he must that Government officials, not Defendants, perform the calculation. Opp. 16. Instead, Relator now attempts to replace the information actually requested by Government officials with his speculation as to the information they *really* want. Opp. 16-17. But the SAC pleads nothing to suggest that officials consider patent status in setting drug prices: Relator does not plead that they ask drug manufacturers about patent status; track patent litigation; or liaise with the USPTO on patent expiration or invalidation. Patents end all the time, yet the price-setting process described in our opening brief—and not questioned by Relator—simply does not take that into account. Rather, as Relator does not dispute, changes in patent status percolate through to federal drug prices over time through regular market processes. Mot. 28-29.[6] Relator's expectation that manufacturers should guess what information federal officials really want, rather than provide what they ask for, Opp. 17, lacks any basis in law.

Returning to *Escobar*, Defendants neither made, nor were required to make, any representation concerning fair market conditions, fair and reasonable pricing, patent validity, or

[6] Relator's "Cf." citation to a Federal Acquisition Regulation ("FAR") provision is also irrelevant. Whatever role "adequate price competition" might play in setting prices for government acquisition and procurement elsewhere, Opp. 17 (citing 48 C.F.R. § 15.402(a)(2)(i)), it does not apply to "orders placed against Federal Supply Schedules contracts." 48 C.F.R. § 8.404(a).

anything else that could have been misleading as *Escobar* describes. Relator does not identify any "half-truth" or other statement to support a false implication. Relator does not dispute that Defendants submitted claims for reimbursement at the properly calculated and Government-approved price, and Relator has pled nothing to suggest payment officials would have taken that price to represent or imply anything other than being the Government-approved price.

2. Relator's "Tainted Claims" Theory of Falsity Lacks Any Basis in Law.

Unable to identify any false certification tied to a claim for payment, Relator argues instead that every claim was false on account of Defendants' purported fraud on the USPTO in securing the '438 patent in the first instance. The FCA does not support so attenuated a claim of falsity.

Relator begins with promissory fraud, Opp. 10; SAC ¶ 106, which, as explained in our Motion, courts have unequivocally limited to claims brought under a contract, Mot. 29-30. Relator responds that there "is no textual basis to limit fraud-in-the-inducement claims to contracts." Opp. 13. But Relator misunderstands his own claim; "fraud-in-the-inducement" *is* a contract claim. *Id.* The FCA prohibits "false claims," and one way to demonstrate falsity is through fraud-in-the-inducement, a contract theory. *See U.S. ex rel. Marcus v. Hess*, 317 U.S. 537, 542 (1943). Under this theory, a claim for payment can be false if entitlement to the payment is based on a fraudulently obtained contract. *See id.* "In other words," as the Ninth Circuit has put it, "subsequent claims are false because of an *original fraud*." *U.S. ex rel. Hendow v. Univ. of Phx.*, 461 F.3d 1166, 1173 (9th Cir. 2006). Thus, cases such as *Hendow* involve the inducement of a contract through a false certification of eligibility. *See id.*

Congress accepted *Hess*'s construction of the FCA as embracing promissory fraud, but recognized that this theory reaches only claims "under a contract, loan guarantee, or other agreement." S. Rep. No. 99-345, at 9 (1986). Given this precedent and legislative history, courts in the Third Circuit have recognized the theory's limitation to *contracts* procured through fraud. *In re Plavix Mktg., Sales Practice & Prods. Liab. Litig.*, 332 F. Supp. 3d 927, 953 (D.N.J. 2017).

Seeking to expand promissory fraud, Relator turns to *U.S. ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890 (9th Cir. 2017). There, the Ninth Circuit devoted only two short

paragraphs to promissory fraud, and its discussion is too scant to throw over the foregoing weight of authority. And in any event, *Campie* does not stretch the law so far as Relator contends.

The defendant in *Campie*, Gilead, had secured FDA approval to manufacture anti-retroviral drugs using ingredients from specific approved sources, but subsequently sold and claimed payment for drugs containing ingredients from unapproved sources. *Id.* at 895-97. Relator cites *Campie* as having dispensed with the contract requirement for promissory fraud. Not so. As the Ninth Circuit described, "[u]nder this theory, liability will attach to each claim submitted to the government *under a contract*, when the contract or extension of the government benefit was originally obtained through false statements or fraudulent conduct." *Id.* at 902 (emphasis added). The Ninth Circuit thus equated a claim for payment made under a contract secured through fraud with a claim for payment made under a specific grant of eligibility secured through fraud.[7] The grant of eligibility in question was very closely tied to the claim for payment; indeed, it was "integral to a causal chain leading to payment." *Id.* at 903. As the Ninth Circuit described, "Gilead lied to the FDA to secure approval of Chinese facilities, making them eligible for government payments (promissory fraud)." *Id.* at 899. This was legally sufficient. *Id.* at 904.

Here, Relator has pled no facts to show that Defendants lied to the officials responsible for determining Zytiga's eligibility for reimbursement or who set the federal pricing. Relator has not pled that Defendants supplied the wrong pricing data, nor has Relator pled anything to show that federal officials inquired into, or viewed as material, Defendants' patent (unlike how the FDA asked Gilead for specific representations about ingredient sources). There was, thus, no material misrepresentation or omission to support even *Campie*-style liability. Relator, rather, seeks to use *Campie* to range vastly further upstream to statements made to the USPTO completely unrelated to eligibility for participation on the FSS. *Campie* does not reach so far.[8]

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[7] The Ninth Circuit similarly treated the relator's factual falsity claim as a claim for non-conforming goods, which also sounds in contract. *Campie*, 862 F.3d at 900; Cal. Com. Code §§ 2601 (buyers' rights on improper delivery), 2711 (buyers' remedies in general).

[8] *Amphastar Pharmaceuticals Inc. v. Aventa Pharma SA*, No. EDCV-09-0023, 2012 WL 5512466 (C.D. Cal. Nov. 14, 2012), is equally unavailing. The court dismissed the Complaint for failing to

Unable to rely on promissory fraud, Relator grafts onto it a series of decisions where the alleged fraud was antecedent to the submission of a claim, and on that basis argues that fraud on the USPTO renders false all subsequent claims for reimbursement. These cases, however, do not support Relator's theory. Rather, each presents a case where the misrepresentation or omission was so causally tied to the claim for payment as to be "integral" or part of the same process.

In *U.S. ex rel. Main v. Oakland City University*, 426 F.3d 914, 916 (7th Cir. 2005), for example, the Seventh Circuit held that where a university participated in a two-step application process—first confirming its eligibility for a grant, and second securing the grant—the university could not launder fraud by parking it in the first step. There, the second-stage application specifically relied on the first stage certification, which, much like *Escobar*, inaccurately implied eligibility. The two steps formed a single application process. The Ninth Circuit's decision in *Campie* is similar. Because the defendant's material omission concerning its mis-sourced ingredients was "integral to a causal chain leading to payment," it was sufficient for FCA liability.

Relator's other cases reflect similarly close causal relationships that his allegations lack. *U.S. ex rel. Garbe v. Kmart Corp.*, 824 F.3d 632, 639 (7th Cir. 2016), is a straightforward case of express false certification. Federal law required pharmacies to charge Medicare Part D customers their "usual and customary" price. *Id.* at 636-37. The defendant charged different customers different prices, and then used only the high prices as its "usual and customary" price for those Medicare Part D customers. *Id.* at 637-38. The defendant simply lied about its pricing.

So too *U.S. ex rel. Krahling v. Merck & Co.*, presented a classic case of factual falsity, no different than the sort of military-contractor fraud that motivated the original False Claims Act during the Civil War, 44 F. Supp. 3d 581, 594-95 (E.D. Pa. 2014), which Relator concedes he has not alleged. Opp. 8-9. Defendant there lied to the Government about the efficacy of its mumps vaccine, selling the Government lots of the vaccine accompanied by false labeling and failing to disclose material information about the vaccine that, if disclosed, would have altered the

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allege the submission of a claim, *id.* at *11-13, and the Ninth Circuit subsequently affirmed dismissal under the public disclosure bar. *See* 856 F.3d 696 (9th Cir. 2017).

Government's willingness to buy it. 44 F. Supp. 3d at 594-95.

These cases all share a close causal connection between a false statement to secure eligibility and a subsequent claim for payment relying on that eligibility. A patent application is not an application for FDA approval or program eligibility. Issuance of a patent does not lead inexorably to the submission of a claim for reimbursement, and eligibility for drug reimbursement is not conditioned on patent coverage. One simply does not cause the other. Relator cites no case supporting FCA liability based on events as remote as a patent application and a claim made later to a different agency for reimbursement at an approved price for sale of a product, which would be eligible for sale to the Government independent of that patent. Issuance of a patent is not closely or causally tied to a claim for payment for a drug. To read these cases otherwise would be inconsistent with *Escobar*, which as discussed, requires specific statements made in connection with the submission of a claim for payment to support falsity. Mot. 24-26.

3. Patent Prosecutions Are Not False Claims Actionable Under The FCA.

Relator asserts a theory that appears nowhere in the SAC (or its predecessor): that the patent application itself was a false claim. Opp. 19-20. *See Jannarone v. Sunpower Corp.*, No. 18-9612, 2018 WL 5849468, at *2 (D.N.J. Nov. 7, 2018) (plaintiff may not amend complaint in opposition to motion to dismiss). This "Hail Mary" claim is demonstrably wrong.

First, Relator cites no authority that a patent application could be an actionable false claim. Relator argues that because patents are intellectual property, a patent application must, therefore, necessarily be a claim. Opp. 19. But there are numerous programs under which an applicant may seek assignable rights that are subsequently treated as property, but which do not involve a government payment—such as, for example, drug approvals. In one blow, Relator would expand the FCA to reach all such applications for "property" no matter how attenuated from the presentation of a claim for payment, while divorcing such claims from the FCA's purpose of protecting the United States against economic loss through fraud. *See, e.g.*, *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 182-84 (3d Cir. 2001) (submission of fraudulent legal bills for bankruptcy court approval does not implicate financial loss to the United States and therefore falls

outside the FDA; citing cases); *see also Dookeran v. Mercy Hosp. of Pittsburgh*, 281 F.3d 105, 109 (3d Cir. 2002) (application that would not result in authorization of federal funds not a claim under the FCA); *U.S. ex rel. Sequoia Orange Co. v. Oxnard Lemon Co.*, No. CV-F-91-194, 1992 WL 795477, at *3 (E.D. Cal. May 4, 1992) (FCA encompasses claims that "caused or are capable of causing financial loss to the Government").

A patent, let alone a not-yet-existing one, has no value to the Government. *Sequoia Orange Co.*, 1992 WL 795477, at *4 (shipping allotments have no intrinsic value to Government). The creation and issuance of a new patent does not itself inflict fiscal harm to the Government; any subsequent economic loss can result only from a transaction attenuated and independent from the grant. Far from being an actionable false claim, this new (waived) theory highlights the disconnect between the alleged misconduct and any claim for payment. It should be rejected.[9]

B. Relator Fails To Plead Materiality.

The SAC fails to meet *Escobar*'s "demanding" materiality standard. Mot. 30-32. Relator's speculation about what might be material to a "reasonable payor" does not pass muster. Opp. 21. *Escobar* teaches that the Government's continued payment can be strong evidence of non-materiality. 132 S. Ct. at 2003-04. Relator does not dispute that the Government continues to reimburse claims for Zytiga despite having been alerted repeatedly to Relator's allegations. Mot. 31; *see U.S. ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 490 (3d Cir. 2017) (noting, post-*Escobar*, that "a misrepresentation is not 'material to the *Government's payment decision*,' when the relator concedes that the Government would have paid the claims with full knowledge of the alleged noncompliance"). And Relator's invocation of sundry enforcement tools cuts against his claims, as the Government has not elected to use them here. Opp. 21-22. Indeed, Relator's objections, Opp. 22-23, are belied by the Federal and State Governments' unanimous decision to

[9] Relator attempts to distinguish the FCA from statutory regimes in which inequitable conduct may not serve as a predicate offense, reasoning that, unlike those regimes, "the FCA is not limited to attempts to obtain property in the government's hands" as it is not concerned with *who* has title to that property. Opp. 19-20 n.8. But this misses the forest for the trees. An unissued patent is not property and no one, the Government or anyone else, holds title to it—it simply does not exist.

not intervene in support of Relator's allegations. Relator's suggestion, Opp. 23, that the Government may have "good reasons unrelated to materiality" to pay a claim while knowing of a violation ignores *Escobar*'s demanding test for materiality.

Importantly, despite our invitation to do so, Relator still fails to identify any statute, regulation, or other requirement that hinges the establishment of a federal drug price, or reimbursement at that agreed price, on the validity of a patent.[10] Rather, Relator once again offers only his own speculation as to what the Government would *prefer*. To be sure, any reasonable payer may *prefer* to pay less. Opp. 21. But here, the Government established a process for determining what it would pay, including identifying the criteria upon which it would calculate the appropriate price and base its reimbursement decisions. The only permissible, non-speculative inference as to what the Government *prefers* here are the steps set out in the Government's pricing regulations, which make no provision for changes in patents. Relator's musings to the contrary fall far short of any required pleading standard. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

Relator's own authorities demonstrate how to plead materiality to substantiate an FCA claim. *E.g. U.S. ex rel. Grubea v. Rosicki, Rosicki & Assocs., P.C.*, 318 F. Supp. 3d 680, 701 (S.D.N.Y. 2018) (exhaustively detailing various certifications and regulatory requirements); *U.S. v. DynCorp Int'l, LLC*, 253 F. Supp. 3d 89, 105 (D.D.C. 2017) (examining the applicability of the FAR's reasonableness provision); *U.S. v. Rite Aid Corp.*, No. 2:11-cv-11940, 2018 U.S. Dist. LEXIS 61030, at *18-19 (E.D. Mich. Apr. 11, 2018) (applicability of relevant regulatory term uncontested). Here, Relator points to no comparable allegation or regulatory requirements.[11]

III. RELATOR FAILS TO PLEAD INEQUITABLE CONDUCT BEFORE THE USPTO

[10] Relator also argues that Defendants' submission to the USPTO regarding non-obviousness was material to the agency's decision that the proposed patent was not obvious. Opp. 21. Relator's unpled claim that a patent application can constitute a false claim is addressed *supra*.

[11] Relator cites *Garbe* as "particularly instructive." Opp. 22. There, however, the Defendant purposefully gamed the relevant pricing regulations and effectively lied about the "usual and customary" prices it was charging. 824 F.3d at 636-37. Here, in contrast, Relator pleads nothing to support any claim that Defendants supplied anything other than the information specified by the Government to allow Government officials to calculate the "fair and reasonable" price.

Ultimately, each of Relator's claims devolves to the contention that Defendants secured the '438 patent by defrauding the USPTO. If Relator cannot plead and prove fraud on the USPTO—inequitable conduct—every subsequent claim fails.

Relator asserts first that he need not plead inequitable conduct. Opp. 26. But Relator's claims hinge on fraud on the USPTO that would have invalidated the patent. Because this FCA claim turns on an underlying violation, Relator must adequately plead that underlying violation—including any applicable scienter requirement—in addition to the FCA's own requirements. *See U.S. ex rel. Bookwalter v. UPMC*, 938 F.3d 397, 415 (3d Cir. 2019); *see also U.S. ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656, 665 (W.D. Pa. 2014); *U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*, No. 1:05-CV-2184, 2010 WL 1390661, at *5 (M.D. Pa. Mar. 31, 2010). Here, to allege fraud on the USPTO, Relator must meet the Federal Circuit's "inequitable conduct" standard for fraud on the USPTO.[12] Mot. 33-34. Moreover, contrary to Relator's contention, Opp. 28, scienter is properly raised at the motion-to-dismiss stage. *See, e.g.*, *Mycone Dental Supply Co. v. Creative Nail Design, Inc.*, No. 11-4380, 2013 WL 3216145, at *7 (D.N.J. June 24, 2013).

Relator repeats his generalized claim that the J&J Defendants had the requisite intent to engage in fraud before the USPTO. Opp. 27. But the focus for the duty of candor is on individuals. Mot. 33. Pointing to allegations recounting actions taken by Defendants collectively or generally concerning the '438 Patent prosecution is insufficient. Opp. 28 (citing SAC ¶¶ 63-82).

Relator neither refutes nor pleads facts to show that "a *specific individual* both knew of invalidating information that was withheld from the PTO and withheld that information with a specific intent to deceive the PTO." *See Delano Farms Co. v. Cal. Table Grape Comm'n*, 655 F.3d 1337, 1350 (Fed. Cir. 2011) (emphasis added). For instance, while Relator suggests that Mr. Auerbach *may* have been in a position to know allegedly withheld information, Relator does not assert that Mr. Auerbach then withheld that information with a specific intent to deceive. Opp. 29

[12] When, as here, patent-related issues arise in non-patent cases, Federal Circuit law governs the patent issues. *See Nobelpharma AB v. Implant Innovations*, 141 F.3d 1059, 1068 (Fed. Cir. 1998) (applying Federal Circuit law to patent questions arising in antitrust context).

n.13. Despite the benefit of having seen this same explanation in the J&J Defendants' prior motion to dismiss, Relator still has not pled facts sufficient to meet this standard as to any individual owing a duty of candor to the USPTO. Opp. 29-30.

Nor does Relator plead that the alleged omissions would have been material to the USPTO. Relator does not attempt to show "why" the information he raises is material or "'how' an examiner would have used" the information in considering the patent. *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1329-30 (Fed. Cir. 2009); *see, e.g.*, SAC ¶ 84(e) (claiming improper market-share metric without evaluating effect on examiner); SAC ¶ 121 ("But for Defendants' misrepresentations to the Patent Office concerning Zytiga's purported commercial success as alleged herein, the Patent Office would never have issued the '438 Patent."). For example, Relator makes much of the fact that Xtandi was not FDA-approved for the chemo-naïve market at the time of J&J's comparison, but never pleads facts explaining the importance—let alone the relevance—of FDA-approval status to sales in oncology patient sub-markets. In short, Relator cannot plead the predicate conduct around which his entire suit is built, and the SAC should be dismissed.

IV. ALL CLAIMS AGAINST BTG SHOULD BE DISMISSED WITH PREJUDICE

As to BTG, Defendants explained (Mot. 36-38) that the Second Amended Complaint lacks factual allegations on two separate, required prongs of the FCA—that BTG either (1) participated in the alleged, underlying fraud or (2) knew about it. In opposing dismissal, the Relator ignores these arguments, conceding both points. Relator merely asserts without factual allegations that BTG "Participated in the Fraud" (point heading) and "was involved in all of that subsequent misconduct." Opp. 30. Dismissal of the claims against BTG is required under *Twombly* and *Iqbal*. Because Relator fails to contend that he could cure the omission of specific factual allegations that BTG participated in or knew of the fraud (or was reckless in not knowing about it), the Court should dismiss his claims against BTG with prejudice.

The SAC alleges, and Relator argues, only that BTG: (1) became a co-owner of a patent after it issued, and (2) was "involved" in litigation enforcing that patent. Aside from Relator's improper group pleading, there is no allegation whatsoever about BTG's knowledge of the alleged

fraud. Opp. 30; SAC ¶¶ 25, 91, 102-103.[13] These allegations are insufficient to plead that BTG acted with scienter. 31 U.S.C. § 3729(b)(1). They also fail to allege that BTG engaged in any conduct that would violate the FCA. *See Iqbal*, 556 U.S. at 678.

Specifically, Relator fails to point to any factual allegations that could establish that BTG violated the FCA, 31 U.S.C. § 3729(a)(1)(A)-(B)—namely, that BTG:

- Knowingly presented or "cause[d]" to be presented any claims for payment or approval to government reimbursement programs for Zytiga.
- Knowingly made or "cause[d]" the making of any false statements to any government agency (much less any government reimbursement program) relating to the pricing of Zytiga, or claims for Zytiga.

The FCA's proximate-cause standard reinforces the fatal deficiencies of Relator's pleading against BTG. Relator cannot drag BTG into this case by contending only that BTG "was involved" in an attenuated, "but-for" causal chain of alleged falsity; this falls short of alleging proximate causation arising from BTG's specific, alleged conduct. Opp. 30; *see, e.g.*, *U.S. v. Hibbs*, 568 F.2d 347, 349 (3d Cir. 1977) (holding that "a causal connection must be shown between loss and fraudulent conduct and that a broad 'but for' test is not in compliance with the statute"); *U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 714 (10th Cir. 2006) (describing FCA's proximate-cause standard as "winnowing . . . claims with only attenuated links between the defendants' specific actions and the presentation of the false claim"), *overruled on other grounds by Cochise Consultancy, Inc. v. U.S. ex rel. Hunt*, 139 S. Ct. 1507 (2019); *U.S. v. President & Fellows of Harvard Coll.*, 323 F. Supp. 2d 151, 186-87 (D. Mass. 2004) ("To 'cause' the presentation of false claims under the FCA, some degree of participation in the claims process is required."); *U.S. ex rel. Polansky v. Exec. Health Res., Inc.*, 196 F. Supp. 3d 477, 512-14 (E.D. Pa. 2016) (similar). Merely co-owning and enforcing a patent is not enough.

Neither of Relator's two Opposition arguments can save its claims against BTG. First, Relator contends BTG could be jointly and severally liable "even if [BTG] was not present when

[13] Relator concedes the SAC violates Rule 9(b)'s prohibition on group pleading. Mot. 38.

the Patent Office was first defrauded." Opp. 30. But it is fundamental that joint-and-several liability cannot establish liability; it only apportions liability. *Cf.* Restatement (Third) of Torts: Apportionment Liab. § 12 (2000) (noting that "[e]ach person *who commits a tort*" may be jointly and severally liable for harm caused by that conduct) (emphasis added). The two joint-and-several-liability cases that Relator cites (Opp. 30), *Mortgages* and *Bourseau*, clarify this distinction and undermine Relator's argument. The Ninth Circuit in *Mortgages* (where joint-and-several liability was not contested) noted that the concept applied only "[w]here one or more persons have *committed* a fraud." *Mortgs., Inc. v. U.S. Dist. Court*, 934 F.2d 209, 212 (9th Cir. 1991) (emphasis added) (granting mandamus petition; ordering dismissal of counterclaim to plaintiffs' FCA complaint). Similarly, in *Bourseau*, the court noted that the concept (again, not contested in that case) applied "[w]here one or more persons have *acted together* to submit false claims . . . ." *U.S. v. Bourseau*, No. 03-cv-907-BEN (WMC), 2006 U.S. Dist. LEXIS 100313, at *36 (S.D. Cal. Sept. 27, 2006) (emphasis added). Here, because Relator alleged no statutory basis for FCA liability against BTG in the first place, joint-and-several liability is irrelevant.

Second, Relator cites no law supporting his contention that merely owning a patent could give rise to FCA liability. *In re Rembrandt Techs., LP Patent Litig.*, 899 F.3d 1254 (Fed. Cir. 2018), is both legally irrelevant and factually inapposite. Opp. 30. The Relator seeks to impose liability under the FCA for allegedly false claims seeking reimbursement from government payors (about which *Rembrandt* says nothing), not for inequitable conduct at the USPTO (as in *Rembrandt*, 899 F.3d at 1272-75) or fraudulently enforcing a patent in federal court. The Court should dismiss Relator's claims against BTG with prejudice.

CONCLUSION

All claims against all Defendants should be dismissed for the reasons stated in Parts I through III above. But in any event, the claims against BTG should be dismissed for the additional and independent reasons set forth in Part IV. And, as this represents Relator's third bite at the apple, the Court should dismiss the SAC with prejudice.

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Respectfully submitted,

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